



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,431	07/18/2003	Jay D. Kranzler	CYPR 100 CIP CON	4067
7278	7590	03/18/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,431	<b>Applicant(s)</b> KRANZLER ET AL.	
	<b>Examiner</b> Rebecca Cook	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

In view of the amendments to claims 53 and 55 the earlier rejections under 35 USC 112, paragraph two are overcome.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50, 52 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by EMBASE AN 1998129084, EMBASE AN 90228858, WO 97/35584, Ninan or FR 2, 752 732. Each reference teaches an SNRI. The claims appear to differ over the references in reciting instructions. However, new instructions to an existing product do not impart patentability. In re Ngai et al, FC 03-1524.

Claims 26, 28-29, 32-33, 35, 39-41, 43, 47-48, 56, 58, 60, 61, 63, 65-66, 70-71, 73, 75 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/32178. WO 00/32178 (page 1, line 15, page 6, line 15 through page 7, line 5, page 30, line 9) discloses a method of using a SNRI to treat pain of CFS and FMS using sibutramine. Some dependent claims appear to differ over WO 00/32178 in reciting that the SNRI has NMDA receptor antagonistic properties. However, it would be inherent that a compound that yields the instant method has said properties.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 28-35, 37-43, 45-50, 56, 58-61, 63-66, 68-71, 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/32178 in view of Ninan.

WO 00/32178 (page 1, line 15, page 6, line 15 through page 7, line 5, page 30, line 9) discloses a method of using a SNRI to treat pain of CFS and FMS using sibutramine.

Dependent claims differ over WO 00/32178 in reciting that the SNRI has NMDA receptor antagonistic properties, that it is administered adjunctively with a second compound and that the SNRI is formulated in a sustained release dosage formulation.

However, it would be inherent that a compound that yields the instant method has said properties. Furthermore, Ninan discloses a method of using sibutramine, also a SNRI compound to treat symptoms of fibromyalgia. Additionally, it would be obvious to combine another antidepressant, analgesic, muscle relaxant, stimulant, sedative or hypnotic with a SNRI to treat pain or other symptoms of CFS or FMS, since they are used in the art to ameliorate said pain and other symptoms. Moreover, no unobviousness is seen in using a sustained release dosage formulation, since it is conventional and known in the art.

Art Unit: 1614

Claims 50-55 are again rejected under 35 U.S.C. 103(a) as being unpatentable over EMBASE AN 1998129084 or EMBASE AN 90228858 for the reasons given in the Paper of September 29, 2004.

Applicants argue that it would not have been obvious to assemble a kit including an SNRI with instructions for treating CFS, FMS or pain, because methods for treating these conditions with an SNRI are nonobvious. This is not persuasive. New instructions to an existing product do not impart patentability. In re Ngai et al, FC 03-1524.

In view of applicants amendment to the claims the earlier rejection over WO 01/26623 is withdrawn. In view of applicants arguments the earlier rejection over Moreau in view of Woerz is withdrawn.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,602,911,

Art Unit: 1614

6,635,675 and copending Application No.10/623,378 for the reasons given in the Paper of September 29, 2004. It is noted that the Applicants have not argued these rejections or filed Terminal Disclaimers, so the rejections are proper and are maintained.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook



Primary Examiner  
Art Unit 1614

March 10, 2005